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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,539	10/17/2003	Joel S. Echols	32328US02	1150

47231 7590 02/16/2010

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EXAMINER	
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ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
02/16/2010	PAPER

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JOEL S. ECHOLS,
FRANK J. HOLLY, and WOLFGANG WIDERA

Appeal 2009-010387
Application 10/688,539
Technology Center 1600

Decided: February 16, 2010

Before DEMETRA J. MILLS, LORA M. GREEN, and
STEPHEN WALSH, *Administrative Patent Judges*.

WALSH, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134(a) involving claims to opthalmic compositions. The Patent Examiner rejected the claims as indefinite and obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm-in-part.

STATEMENT OF THE CASE

The invention concerns "artificial tear formulations for the treatment of dry eye syndrome and protection of the ocular surface." (Spec. 1:8-9). Claims 1-6, which are all the pending claims, are on appeal. The claims read as follows:

1. The composition for ophthalmic use, comprising:
   a) polyvinyl alcohol;
   b) polyvinyl acetate;
   c) a hydrophilic polymer; and
   d) a phospholipid.

2. The composition of claim 1 wherein said phospholipid is formulated in polysorbate-80, glycerin, ethanol, and water.

3. The composition of claim 1 wherein said phospholipid is lecithin.

4. The composition of claim 1 further comprising water, one or more electrolytes to contribute to the well being of the corneal epithelium, one or more preservatives, and one or more buffers.

5. The composition of claim 1 wherein said hydrophilic polymer is polyvinyl pyrrolidone.

6. The composition of claim 5 wherein the concentration of said polyvinyl alcohol is from about 0.5% to 10% by weight in water, said polyvinyl alcohol being about 96% to 99% hydrolyzed; the concentration of said polyvinyl acetate is from about 0.5% to 10% by weight in water, said polyvinyl acetate being about 73% to 93% hydrolyzed; the concentration of said polyvinyl pyrrolidone is from about 0.5% to 10% by weight in water; and the concentration of said phospholipid is from about 0.003% to 0.02% by weight in water.

The Examiner rejected the claims as follows:

- claims 1-6 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention;
- claims 1-6 under 35 U.S.C. § 103(a) over Suzuki[1], Guy[2] and Holly[3]; and
- claims 1-6 under 35 U.S.C. § 103(a) over Suzuki, Guy, Holly and Applicant's Statements of Prior Art.

INDEFINITENESS

The Issue

The Examiner found that "[t]he distinction between the hydrophilic polymer and the polyvinyl acetate and polyvinyl alcohol in claim 1 is unclear." (Ans. 3). The Examiner reasoned that both the acetate and the alcohol are considered hydrophilic polymers, therefore it is unclear whether an additional component is needed to meet the limitation of "hydrophilic polymer," as recited in the claim. (*Id.*).

Appellants contend that a skilled artisan who read claim 1 in light of the specification would understand that the recitation of a "hydrophilic polymer" means a hydrophilic polymer other than polyvinyl acetate and polyvinyl alcohol. (App. Br. 4). In particular, Appellants assert that the Specification describes mixing polyvinyl acetate and polyvinyl alcohol to

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[1] US Patent No. 6,132,751 issued to Suzuki et al., Oct. 17, 2000.
[2] US Patent No. 5,540,930 issued to Guy et al., Jul. 30, 1996.
[3] US Patent No. 4,883,658 issued to Holly, Nov. 28, 1989.

lower surface tension and then, in the next paragraph, describes including a hydrophilic polymer to achieve a certain oncotic pressure. (*Id.*). Regarding claim 5, Appellants additionally assert there is no confusion about the distinction between the hydrophilic polymer and the polyvinyl acetate and polyvinyl alcohol because "claim 5 recites that the hydrophilic polymer of claim 1 is polyvinyl pyrrolidone." (*Id.* 5; Reply Br. 2).

The issue for decision is whether claims 1-6 are indefinite.

Findings of Fact

1. The Specification states that "[a]ny known hydrophilic polymer can be used but polyvinyl pyrrolidone (povidone) is preferred." (Spec. 5:24-25).
2. Appellants do not dispute that polyvinyl alcohol and polyvinyl acetate are hydrophilic polymers. (*See* App. Br. 4-5).

Principles of Law

The test for definiteness under 35 U.S.C. § 112, second paragraph, is whether "those skilled in the art would understand what is claimed when the claim is read in light of the specification." *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576 (Fed. Cir. 1986) (citations omitted). "[D]uring patent prosecution when claims can be amended, ambiguities should be recognized, scope and breadth of language explored, and clarification imposed. When the applicant states the meaning that the claim terms are intended to have, the claims are examined with that meaning, in order to achieve a complete exploration of the applicant's invention and its relation to the prior art." *In re Zletz*, 893 F.2d 319, 321

(Fed. Cir. 1989). "[I]f the claims do not 'particularly point[ ] out and distinctly claim[ ]', in the words of section 112, that which examination shows the applicant is entitled to claim as his invention, the appropriate PTO action is to reject the claims for that reason." *Id.* at 322. "[D]uring examination proceedings, claims are given their broadest reasonable interpretation consistent with the specification." *In re Hyatt*, 211 F.3d 1367, 1372 (Fed. Cir. 2000).

Analysis

I. Claims 1-4

Appellants do not dispute that both polyvinyl alcohol and polyvinyl acetate are hydrophilic polymers. Rather, Appellants contend that their Specification provides clarification that the alcohol and acetate components of the composition are separate and distinct from the recited "hydrophilic polymer." (*See* App. Br. 4)(citing Spec. p. 5). The portion of the Specification that Appellants rely upon describes (a) mixing the polyvinyl acetate and the polyvinyl alcohol to lower surface tension, and (b) that the "invention has a hydrophilic polymer … to achieve an oncotic pressure of at least 45 millimeters of mercury…." (Spec. 5:22-24).

We do not find these portions enlightening. The Specification does not describe the hydrophilic polymer as a separate and distinct component from the acetate or alcohol. Nor does the Specification limit the "hydrophilic polymer" to specific compounds. To the contrary, the Specification expressly states that "[a]ny known hydrophilic polymer can be used …." (*Id.* 5:24-25). Therefore, when viewed in light of the Specification, one of ordinary skill in the art would understand that the

hydrophilic polymer recited in claim 1 may be "any known hydrophilic polymer," including polyvinyl acetate or polyvinyl alcohol. *See Orthokinetics,* 806 F.2d at 1576; *Hyatt*, 211 F.3d at 1372; *Zletz*, 893 F.2d at 321.

As written, claim 1 recites a formulation comprising two specific hydrophilic compounds (listed as "a) polyvinyl acetate" and "b) polyvinyl alcohol") and an unspecified or generic hydrophilic polymer. This recitation is comparable to, for example, a beverage formulation defined as comprising orange juice, grapefruit juice and a citrus juice. The first two juices are each citrus juices, and it is unclear whether the first two juices satisfy the recitation of a citrus juice, or whether a different citrus juice is required. We conclude that Appellants have not established that the Examiner erred in rejecting claims 1-4 as indefinite.

II. Claims 5-6.

Regarding claims 5 and 6, which both specifically limit "c) a hydrophilic polymer" to polyvinyl pyrrolidone, we agree with Appellants that these claims are not indefinite. By limiting the hydrophilic polymer to a specific compound that is different than the polyvinyl alcohol and polyvinyl acetate hydrophilic polymers, the claim language clarifies that "c) a hydrophilic polymer" is a different compound from and in addition to the alcohol and acetate components. We conclude that the Examiner erred in rejecting claims 5 and 6 as indefinite.

OBVIOUSNESS

The Issue

Have Appellants established that the Examiner erred in determining that it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the known elements of the prior art for their known functions to arrive at the claimed subject matter?

Findings of Fact

3. Suzuki disclosed an emulsion composition for eye drops comprising an anti-inflammatory drug and a phospholipid, such as lecithin, water and liquid paraffin. (Suzuki, 1:1-18; 4:17-20).
4. Suzuki disclosed that the composition provided excellent solubility of the anti-inflammatory drug. (*Id.* at 2:2-4).
5. Suzuki disclosed that the composition may also include sugars, isotonizing agent such as glycerol, pH adjusting agents, preservatives, and thickeners, including polyvinyl pyrrolidone and polyvinyl alcohol. (*Id.* at 6:54-64).
6. Suzuki disclosed that the emulsion could be prepared by a variety of known methods, such as dissolving the phospholipids, emulsifying adjuvants and drug "in an appropriate organic solvent such as hexane or ethanol, followed by distilling off the solvent …." (*Id.* at 7:37-45).
7. Holly disclosed an ophthalmic solution for treatment of dry-eye syndrome comprising a polyvinyl acetate, polyvinyl alcohol, and a hydrophilic polymer such as poly(N-vinyl pyrrolidone). (Holly Abstract; 3:52-4:6; 5:5-9).

8. Holly disclosed that the synergistic combination of the polyvinyl acetate and the polyvinyl alcohol lowered the surface tension of the solution while forming a completely wettable absorbed layer over hydrophobic solids. (*Id.* Abstract; 4:25-29).
9. Holly disclosed that the formulation effectively treated the two major underlying causes of dry eye syndrome: ocular surface disorder and tear film abnormalities resulting in tear film instability. (*Id.* Abstract).
10. Holly also disclosed adding appropriate buffering agents and preservatives to the composition of the invention. (*Id.* Ex. II).
11. Guy disclosed a composition comprising a water-insoluble steroid drug for ear, eye and nose treatment. (Guy abstract; 3:2-4).
12. Guy disclosed that the suspensions also comprised a nonionic polymer, such as polyvinyl pyrrolidone, a nonionic surface active agent, such as polysorbate 80 and TWEEN 80, and could include a tonicity agent, such as glycerol, and preservatives. (*Id.* at 3:10-29; 4:9-18).
13. Appellants' Specification stated that Amisol® Clear, a product that was readily available on the market at the time of the invention, "contain[ed] phospholipids (lecithin), polysorbate-80, glycerin and ethanol." (Spec. 5:30-6:2).

Principles of Law

"The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR International Co. v. Teleflex Inc.*,550 U.S.,398, 416 (2007). There must be some articulated reasoning with some rational underpinning to support

the legal conclusion of obviousness. *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006). It is the Applicants' burden to precisely define the invention. *In re Morris*, 127 F.3d 1048, 1056 (Fed. Cir. 1997). "Express suggestion to substitute one equivalent for another need not be present to render such substitution obvious." *In re Fout*, 675 F.2d 297, 301 (CCPA 1982).

Analysis

I. Suzuki, Guy and Holly.

A. The Rejection

The Examiner's position is that Suzuki disclosed emulsion compositions for eye drops comprising water, phospholipids such as lecithin, polyvinyl alcohol, the hydrophilic polymer polyvinyl pyrrolidone, isotonizing agents such as glycerol and solvents such as ethanol. (Ans. 3)(citing Suzuki 4:17-26; 6:54-67, 7:33-44 and Examples). However, the Examiner also found that Suzuki did not teach adding polyvinyl acetate to the composition, as recited in instant claim 1, or polysorbate-80 (Tween 80), as recited in instant claim 2. (*Id.*).

The Examiner found that Guy disclosed eye formulations comprising water, polyvinyl pyrrolidone, polyvinyl alcohol, glycerol and Tween 80. (*Id.* 4)(citing Guy 2:4-5, 3:10-4:19). Additionally, the Examiner found that Holly disclosed ophthalmic solutions for treating dry-eye syndrome and taught that "the combination of an aqueous solution of a partially hydrolyzed polyvinyl acetate and polyvinyl alcohol is synergistic." (Ans. 4)(citing Holly Abstract and 3:51-5:27).

According to the Examiner, the addition of polyvinyl acetate to the composition of Suzuki would have been obvious to one of ordinary skill in

the art at the time the invention was made because Holly taught that the combination of polyvinyl acetate and polyvinyl alcohol is beneficially synergistic. (*Id.*). Further, the Examiner determined that it would also have been obvious to a skilled artisan at the time of the invention to include a surfactant such as Tween 80 (polysorbate-80) in the formulation of Suzuki because Guy taught the use of a non-ionic surfactant such as Tween 80 in ophthalmic formulations. (*Id.*).

B. Appellants' Contentions

1. Claims 1, 3 and 5.

Appellants contend that the Examiner erred in rejecting claims 1, 3 and 5 because Suzuki "does not disclose using both polyvinyl pyrrolidone [a hydrophilic polymer] and polyvinyl alcohol together in the same composition." (App. Br. 7).

This argument is not persuasive. The fact that Suzuki did not provide an example using both polyvinyl pyrrolidone or polyvinyl alcohol in the same composition does not limit Suzuki's disclosure to the use of *either* polyvinyl pyrrolidone or polyvinyl alcohol. Suzuki expressly taught that "thickeners" (i.e., plural) such as polyvinyl pyrrolidone and polyvinyl alcohol could be added to the composition. (*See* Suzuki, 6:54-64). Given Suzuki's instructions, it would have been obvious and within the skill of the art to include a single thickener or a combination of thickeners in a composition (*see* Ans. 6). Further, as the Examiner found in the Final Rejection, Holly specifically disclosed an opthalmic composition comprising both polyvinyl pyrrolidone and polyvinyl alcohol. (*See* Fin.Rej. 3). Therefore, Holly provided evidence that combining polyvinyl pyrrolidone

and polyvinyl alcohol was known and within the skill in the art at the time of the invention.

Appellants argue that it would not have been obvious to modify Suzuki by adding polyvinyl acetate to its composition comprising polyvinyl alcohol because Holly only taught that the synergistic effect of polyvinyl acetate and polyvinyl alcohol relates to lowering surface tension of a solution used in the treatment of tear film instability and not the problem addressed by Suzuki, that is, improving the solubility of drugs. (App. Br. 8; Reply 3-4). Appellants also assert that the fact that Holly and Suzuki are both drawn to eye treatment compositions "does not provide a convincing line of reasoning to establish the 'rational underpinning' supporting the legal conclusion of obviousness required by *KSR*." (App. Br. 9).

Appellants consider Holly too narrowly. In addition to treating tear film instability, Holly expressly disclosed that its formulation also effectively treated a second major cause of dry eye syndrome, ocular surface disorder. (Holly Abstract). Holly disclosed that many eye complaints related to conditions including an inflammatory reaction "are usually caused by a dry eye state." (Holly, 1:35-40). Moreover, Holly expressly stated that its formulations "can also be effective as an aqueous vehicle for topically used ophthalmic drugs or nutrients." (Holly, Abstract). Suzuki disclosed an eye drop composition comprising drugs "exhibiting a strong anti-inflammatory action," and thickeners including polyvinyl alcohol. (Suzuki 1:16-19; 6:62-64). Suzuki explained that its composition "can effectively be used, in the form of an eye drop, for the treatments of various ocular diseases, for instance, inflammatory diseases of external- and anterior-ocular sites …." (*Id.* at 2:25-29). We agree with the Examiner that it would have

been obvious for a skilled artisan at the time of the invention to modify Suzuki's composition by adding polyvinyl acetate to the polyvinyl alcohol, as taught by Holly, because Holly taught that its synergistic formulation was an effective vehicle for ophthalmic drugs and that the formulation effectively treated a common cause of ophthalmic inflammatory reaction. Therefore, we find that the Examiner articulated sound reasoning with rational underpinnings to support combining the teachings of the prior art to reach the claimed invention. *See Kahn*, 441 F.3d at 988.

Appellants also challenge the rejection of claims 1, 3 and 5 by asserting "that the composition of claim 1 does more than yield predictable results." (*Id.*). According to Appellants, the claimed elements work together in an "unexpected and fruitful manner" so as to replicate all three layers of the normal human tear film. (*Id.* at 9-10)(citing Spec. 4:16-18).

While Appellants' Specification states that the composition of invention replicates all three layers of the normal human tear film, the Specification does not describe or suggest that such a result was unexpected by the combination. Rather, the Specification describes that it was known in the art that the normal human tear film comprises a mucin layer, an aqueous layer and a lipid layer, and that products existed incorporating ingredients/components mimicking each of these layers. (*See* Spec. 1:15-20; 4:3-8). Consequently, we do not find that Appellants have established that their invention provided an unexpected result by replicating all three layers of the normal human tear film.

2. Claim 2.

Appellants contend that the Examiner erred in rejecting claim 2 by asserting that the combination of Suzuki, Guy and Holly "fails to suggest

using a phospholipid formulated in polysorbate-80, glycerin, ethanol, and water." (App. Br. 10). In particular, Appellants assert that the Examiner's modification of Suzuki with Guy's teaching to add polysorbate-80 in an eye formulation comprising glycerol is not supported by any "rational underpinning." (*Id.* at 10-11). Additionally, Appellants assert that Suzuki does not suggest using a phospholipid formulated in ethanol because Suzuki described using ethanol "for preparing the emulsion," but then described that the solvent is subsequently distilled off. (*Id.* at 11; Reply 5). Therefore, according to Appellants, "the finished composition of Suzuki et al does not contain any ethanol because any ethanol used [in] the preparation of the emulsion is distilled off." (Reply Br. 5)(citing Suzuki 7:44-46).

We do not find Appellants argument to be commensurate in scope with the language of claim 2. Claim 2 recites that the "phospholipid is formulated in polysorbate-80, glycerin, ethanol, and water." Appellants' arguments seems to suggest that this claim phrase requires "the finished composition" to *contain* ethanol. (*See* Reply Br. 5). However, the claim phrase "formulated in," broadly read, includes a method of preparing, i.e., the phospholipid was formulated in ethanol, and does not require the claimed composition to *contain* or *comprise* ethanol. In other words, claim 2 does not exclude a composition from which ethanol was distilled off after the phospholipid was formulated. While Appellants may have intended a more narrow meaning, it is the Applicants' burden to precisely define the invention. *See Morris*, 127 F.3d at 1056.

3. Claim 4.

Appellants assert that "[t]here is no teaching or suggestion in the prior art of record of using one or more electrolytes that contribute to the well

being of the corneal epithelium, and the Examiner has provided no indication at all as to why this claimed feature would have been obvious." (Appeal Br. 11).

The Examiner found that Holly disclosed an exemplary ophthalmic composition comprising electrolytes, buffers and preservatives. (Ans. 9-10)(citing Holly Example II). The Examiner also found that Guy disclosed adding preservatives and buffers to its compositions. (Ans.10)(citing Guy 5:1-10; Examples 1-37). The electrolytes that Holly disclosed in Example II included sodium chloride and potassium chloride, both of which the Appellants' Specification states are preferable electrolytes "known to contribute to the well-being of the corneal epithelium." (*Compare* Spec. 6:13-15 *with* Holly Ex. II, Table III). Therefore, we do not find that Appellants have established Examiner error.

4. Claim 6.

Appellants assert that "[t]he prior art fail[ed] to teach or suggest [the] claimed concentration levels, and the Examiner has provided no reasoning supporting the position that these claimed concentration levels would have been obvious." (Appeal Br. 12).

We agree with Appellants that the Examiner has not articulated sufficient reasoning to establish that the claimed concentration levels recited in claim 6 are prima facie obvious. *See Kahn*, 441 F.3d at 988.

Accordingly, we affirm the Examiner's rejections of claims 1-5, and reverse the Examiner's rejection of claim 6.

II. Suzuki, Guy, Holly and Applicants' Statements of Prior Art.

A. The Rejection

In rejecting claims 1-6 as obvious over a combination of Suzuki, Guy, Holly and Applicants' Statements of Prior Art, the Examiner found that Suzuki particularly disclosed using lecithin, glycerol, ethanol and water in the composition of the invention. (Ans. 4). The Examiner also found that "[o]n page 6 of the [S]precification, Appellants state that the combination of lecithin, ethanol, glycerol, polysorbate 80 is readily available on the market under the trade name Amisol™." (*Id.* at 5.) According to the Examiner, one of ordinary skill in the art at the time of the invention would have been motivated to use Amisol® Clear because it conveniently provided a premixed solution of the individual components disclosed in the prior art. (*Id.*).

B. Appellants' Contentions

1. Claims 1, 3 and 5.

Appellants contend that "just because a product is commercially available does not mean that it would have been obvious to use that product in the claimed composition." (App. Br. 12-13). Appellants further assert that because the prior art did not teach "using Amisol or a similar product as a source of a phospholipid in the claimed composition," there was no reason or "rational underpinning" for a person of ordinary skill to combine Amisol® Clear with Suzuki, Guy and Holly. (*Id.* at 13).

We do not find that Appellants have established that the Examiner erred in rejecting claims 1, 3 and 5. While Suzuki and Guy did not expressly teach using Amisol® Clear, Suzuki did expressly disclose a composition having each of the ingredients comprised in Amisol® Clear. (See FF-3, 5,

and 6). We agree with the Examiner that it would have been obvious to one of ordinary skill in the art to either combine Suzuki's components individually, or to conveniently use a readily available premixed product containing the components. (Ans.10-11). Such a modification would involve no more that the simple substitution of one known equivalent for another. *See In re Fout*, 675 F.2d 297, 301 (CCPA 1982)("Express suggestion to substitute one equivalent for another need not be present to render such substitution obvious.").

2. Claim 4.

Appellants contend that neither the combined prior art, nor the Appellants' statements of prior art "teach or suggest using one or more electrolytes that contribute to the well being of the corneal epithelium, as recited in claim 4." (*Id.* at 13).

This argument is not persuasive for the same reasons discussed regarding the rejection of claim 4 over the combination of Suzuki, Guy and Holly, i.e., Holly expressly disclosed examples comprising such electrolytes. Consequently, we do not find that Appellants have established error on the part of the Examiner.

3. Claim 6.

Appellants assert that neither the combined prior art, nor the Appellants' statements of prior art "teach or suggest the concentration levels recited in claim 6." (*Id.* at 14).

We agree with Appellants that the Examiner has not established a prima facie case of obviousness regarding the concentration levels recited in claim 6.

Accordingly, we affirm the Examiner's rejections of claims 1-5, and reverse the Examiner's rejection of claim 6.

CONCLUSIONS OF LAW

Those skilled in the art would not understand what is claimed in claims 1-4 when the claim is read in light of the Specification; however, the skilled artisan would understand what is claimed in claims 5 and 6; and

the evidence supports the Examiner's determination that claims 1-5 would have been obvious over the combined prior art to a person of ordinary skill in the art at the time of the invention; however, the Examiner has not established a prima facie case obviousness over the combined prior art regarding claim 6.

SUMMARY

We affirm the rejection of claims 1-4 under 35 U.S.C. § 112, second paragraph, and reverse the rejection of claims 5-6 under 35 U.S.C. § 112, second paragraph;

we affirm the rejection of claims 1-5 under 35 U.S.C. § 103(a) over Suzuki, Guy and Holly, and reverse the rejection of claim 6 under 35 U.S.C. § 103(a) over Suzuki, Guy and Holly;

we affirm the rejection of claims 1-5 under 35 U.S.C. § 103(a) over Suzuki, Guy, Holly and Applicant's Statements of Prior Art, and reverse the rejection of claim 6 under 35 U.S.C. § 103(a) over Suzuki, Guy, Holly and Applicant's Statements of Prior Art.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED-IN-PART

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